

**HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)  
IN HUMAN SUBJECTS RESEARCH**

- 1) **PURPOSE:** To establish a service level policy for conducting research at the Portland VA Medical Center in accordance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This policy will help to ensure the proper use and disclosure of protected health information (PHI) for research participants in research approved and conducted at the Portland VA Medical Center.
- 2) **SCOPE:**
  - a) This policy covers all private health information (PHI) that exists or may be created, used or disclosed by, through or during research activities. This policy applies to all VA paid or without compensation (WOC) employees and contract personnel at VA facilities and approved off-site locations who conduct research and use or disclose PHI in connection with PVAMC IRB-approved research activities.
  - b) All PVAMC VA investigators conducting PVAMC IRB-approved research must obtain authorization to use PHI from the potential research subject in a separate written HIPAA Authorization unless the IRB waives the requirement. All HIPAA Authorizations must be approved by the Privacy Officer.
- 3) **POLICY:** The HIPAA Privacy Rule was effective on April 14, 2003. The final modification to the rule by HHS was published on August 14, 2002 in the Federal Register (Vol. 67, No. 157, pages 53182-53273). The Portland VA Medical Center (PVAMC) Institutional Review Boards (IRBs) serve as the Privacy Boards for research at the PVAMC.
- 4) **DEFINITIONS:**
  - a) **Access** - Access is the collection or use of information electronically, on paper or other medium, for the purpose of performing an official function.
  - b) **Business Associate** - A business associate is an individual, entity, company or organization who, on behalf of the Veterans Health Administration (VHA), performs or assists in the performance of functions or activities involving the use or disclosure of protected health information (PHI) or provides certain services to VHA and the provision of those services involves the disclosure of PHI by VHA. Per Patricia Watts, Office of Research and Development, sponsors are generally not considered business associates because they do not perform or assist in the performance of functions.
  - c) **Covered Entity** - The VHA is a single covered entity for the purpose of complying with the Privacy Rule. This covered entity includes all VHA hospitals and health care systems.
  - d) **De-identified Information** - De-identified information is health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.
  - e) **Designated Record Set** - a group of records maintained by or for VHA that are the medical records and billing records; enrollment, payment, claims, adjudication, and case

or medical management records; or records used, in whole or in part, to make decisions regarding individuals.

- f) **Disclosure** - Disclosure is the release, transfer, provision of access to, or divulging in any other manner information outside VHA. The exception to this definition is when the term is used in the phrase “accounting of disclosures.”
- g) **Health Information** - Health information is any information created or received by a health care provider or health plan that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual. This encompasses information pertaining to examination, medical history, diagnosis, findings or treatment, including such information as laboratory examinations, X-rays, microscopic slides, photographs, prescriptions, etc.
- h) **Individually-identifiable Information** – Individually-identifiable information is any information, including health information maintained by VHA, pertaining to an individual that also identifies the individual and, except for individually-identifiable health information, is retrieved by the individual’s name or other unique identifier. Individual-identifiable health information is covered regardless of whether or not the information is retrieved by name.
- i) **Individually-identifiable Health Information** - Individually-identifiable health information is a subset of health information, including demographic information collected from an individual, that meets the following criteria:
  - i) Created or received by a health care provider, health plan, or health care clearinghouse;
  - ii) Relates to the past, present, or future condition of an individual and provision of or payment for health care; and
  - iii) Identifies the individual or a reasonable basis exists to believe the information can be used to identify the individual. **NOTE:** Individually-identifiable health information does not have to be retrieved by name or other unique identifier to be **covered** by this policy.
- j) **Limited Data Set** - A Limited Data Set is protected health information that excludes specific direct identifiers of the individual or of relatives, employers or household members of the individual. A limited data set is not de-identified data. A limited data set can only be used for the purposes of research, public health, or health care operations, and disclosed for the purpose of research. The use of a Limited Data Set in research requires IRB approval.
- k) **Privacy Board** - “Privacy Board” is a term created by the Standards for Privacy of Individually-identifiable Health Information (45 CFR Parts 160 and 164) to describe a board comprised of members with varying backgrounds and appropriate professional competencies, as necessary, to review the effect of a research protocol on an individual’s privacy rights when an Internal Review Board (IRB) does not. The Portland VA Medical Center (PVAMC) Institutional Review Board(s) (IRB) will serve as the Privacy Board(s) for research at the PVAMC.

- l) **Protected Health Information (PHI)** - PHI is individually-identifiable health information maintained in any form or medium. **NOTE:** PHI excludes employment records held by a covered entity in its role as an employer.
- m) **Research** - For the purposes of this policy, “research” is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.
- n) **VHA Investigator** – A VHA Investigator must be a VHA employee (which includes official WOC employees) or contract personnel. To determine if a researcher is a VHA Investigator contact the Research Service.
- o) **Without Compensation (WOC) Appointment** - A WOC appointment is a personnel appointment by which an individual contributes time to VA activities, but receives no monetary compensation from the VA.

## 5) RESPONSIBILITIES

- a) The **Associate Chief of Staff for Research & Development** is responsible for developing and managing policies and procedures for the creation, use and disclosure of protected health information for research purposes at the Portland VA Medical Center.
- b) The **Research and Development Committee (R&D)** is responsible for the review and approval of policies and procedures regarding the creation, use and disclosure of protected health information for research purposes at the Portland VA Medical Center.
- c) The **Institutional Review Board Chairpersons** are responsible for reviewing and determining the appropriateness and approval for submitted requests regarding preparatory and decedent research.
- d) The **Institutional Review Board** is responsible for assuring an [Authorization for the Use and Disclosure of Protected Health Information for Research Purposes](#) is consistent with the associated research protocol and informed consent form or for reviewing and approving or disapproving a waiver of such an authorization for the creation, access, use and disclosure of protected health information in research projects submitted to the IRB for review.
- e) The **Privacy Officer** is responsible for reviewing and approving or disapproving an [Authorization for the Use and Disclosure of Protected Health Information for Research Purposes](#).
- f) **VHA Investigators and Research Staff** are responsible for:
  - i) Adhering to the policies and procedures set forth in this policy.
  - ii) Adhering to the assurances signed and agreed to with any Institutional Review Board form.
  - iii) Ensuring the confidentiality and protection of any VHA patient protected health information that is created, accessed, used and/or disclosed.

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- iv) Ensuring that any VHA patient protected health information is not disclosed to any other person or entity, except as required by law, research oversight or as deemed acceptable by the IRB.

**6) PROCEDURES:**

**a) Privacy Board for Research:** The Portland VA Medical Center IRBs shall serve as the Privacy Boards for research conducted at the PVAMC. If the PVAMC will use or disclose PHI on the basis of a waiver or an alteration of authorization from a Privacy Board, the board must be established in accordance with Section 164.512(i) of the Privacy Rule. The PVAMC IRBs meet the following provisions:

- i) Members must have varying backgrounds and appropriate professional competencies as necessary to review the effect of the research protocol on individuals' privacy rights and related interests.
- ii) Each board must have at least one member who is not affiliated with the covered entity or with any entity conducting or sponsoring the research and who is not related to any person who is affiliated with such entities.
- iii) Members may not have conflicts of interest regarding the projects they review.

**b) Research Use or Disclosure of PHI with Authorization:**

- i) As a general rule, a researcher must obtain an authorization from all participants in research **prior to** the internal use or external disclosure of PHI for any research related purpose that is not otherwise permitted or required under this policy.
- ii) An authorization for research must be written in plain language and must contain **all** of the following elements present in the PVAMC [Authorization for the Use and Disclosure of Protected Health Information for Research Purposes](#) form.

**c) Procedure for Signing an Authorization:** Written authorization for release of information is valid when signed by the following in order of precedence:

- i) the subject.
- ii) A court-appointed legal guardian. **Note:** *A VA Federal fiduciary administratively appointed by VBA to administer a beneficiary's VA monetary benefits is not empowered to exercise privacy rights of the VA beneficiary who is the subject of that appointment including granting authorization, i.e. Power of Attorney.*
- iii) A person legally authorized in writing by the subject (or the subject's legal guardian) to act on behalf of the subject. If the subject is deceased, then Executor of Estate, next-of-kin, or other person who has authority to act on behalf of the individual.

**d) Waiver of Authorization by IRB:** In some circumstances, research authorizations otherwise required under this policy may be waived or altered by the IRB, provided the criteria listed on the "Request for Waiver of Informed Consent Documentation and Waiver of Authorization to Release Medical Records or Health Information" or the "Request for Waiver or Alteration of Informed Consent Process and Waiver of Authorization to Release Medical Records or Health Information"

([http://www.portland.va.gov/Research/piservices/rd\\_forms.asp#alphabetical](http://www.portland.va.gov/Research/piservices/rd_forms.asp#alphabetical)) are satisfied and approval is documented.

e) **Recruitment of Research Subjects:** The following methods of recruitment are acceptable options for subject recruitment. These recruitment activities require prospective IRB review and approval.

- i) A PVAMC clinician may speak directly with his/her patients who may qualify for and be interested in a particular research project without an authorization.
- ii) A PVAMC investigator may publish an IRB-approved advertisement and potential subjects may call the designated individual directly. If any PHI will be collected during the conversation, the process must receive a waiver of authorization from the IRB. The PHI collected must be the minimum necessary for recruitment for the specific research project. In these situations, an investigator should submit a completed [Application for a Waiver of Authorization and Informed Consent for Screening/Recruitment Purposes](#) to the IRB for review and approval prior to collecting any PHI without obtaining authorization.
- iii) All other uses and disclosures of PHI for the purpose of contacting and/or recruiting potential research participants may require a waiver of authorization. An investigator may be required to submit a completed Partial Waiver of Authorization for Screening/Recruitment Purposes form to the IRB for review and approval, prior to collecting any PHI without obtaining authorization.

f) **Reviews Preparatory to Research:**

- i) VA researchers may access PHI (including VA medical records or other repositories) without an authorization from the subject(s), a waiver of authorization, or approval by the IRB for reviews preparatory to research, e.g., to design a research study or to assess the feasibility of conducting a study. Non-VA researchers may not access VA data for reviews preparatory to research. No approval is necessary from the IRB.  
**NOTE:** Pilot studies are not considered activities preparatory to research, and thus, require IRB approval.
- ii) Prior to accessing any PHI for this purpose, the VA researcher must submit a completed Research Preparation Application ([http://www.portland.va.gov/Research/piservices/rd\\_forms.asp#alphabetical](http://www.portland.va.gov/Research/piservices/rd_forms.asp#alphabetical)) to the R&D Service for review and approval.
- iii) Investigators must comply with all other access requirements set by the repository of interest.

g) **Research on Protected Health Information of Decedents:**

- i) VHA researchers may use and disclose a decedent's PHI for research without an authorization from the subject(s) only after prospective IRB approval has been obtained. Prior to accessing any PHI for this purpose, the VHA researcher must submit a completed [Research on Decedents' Information Application](#) to the IRB for review and approval.

**h) Use or Disclosure of “De-Identified” Health Information:**

- i) De-identified health information is exempt from HIPAA and may be used or disclosed for research purposes without an authorization or IRB waiver.
- ii) Researchers must provide documentation to the IRB, prior to the disclosure of PHI, that the health information has been de-identified by submission of one of the following two forms:
  - (1) IRQ Appendix J – HIPAA: Statistical Analysis De-identification Certification, documenting that a person with appropriate knowledge and experience will apply generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable; or
  - (2) IRQ Appendix I – HIPAA: Safe Harbor De-Identification Certification demonstrating that the risk of re-identification of the data, alone or in combination with other data, is very small and documenting the methods and results by which the health information is de-identified.
- iii) Coded data is considered de-identified if there is a written agreement preventing all members of the research team from accessing or otherwise attempting to ascertain identities or identifiers for data received from a person or entity not involved in the research.

**i) Coded data and Re-identification:** A VHA investigator may assign a code, or other means of record identification, in order to allow information de-identified to be re-identified by VHA, provided that

- i) The code or other means of record identification is not derived from or related to information about the individual and is not otherwise translatable so as to identify the individual;
- ii) The code, or other means of re-identification is not used or disclosed by VHA for any other purpose; and
- iii) VHA does not disclose the mechanism (e.g., algorithm or other tool) for re-identification.
- iv) The code or other means of record identification is not one of the 18 PHI identifiers, nor is it derived from any of the 18 PHI identifiers that must be excluded for de-identification. **NOTE:** *When disclosing de-identified data to non-VA entities the key to the code must be retained and maintained in a secure location by the investigator and not disclosed to any unauthorized individual or entity.*
- v) Coded data is considered identifiable if any member of the research team has access to the key to the code and could thus identify any of the data.

**j) Limited Data Set:**

- i) A researcher may use or disclose a Limited Data Set for research purposes without an authorization or waiver of authorization.
- ii) A “Limited Data Set” is defined as PHI that **may include** any of the following *direct identifiers*:
  - (1) Town, city, State and zip code;

- (2) All elements of dates directly related to an individual, including birth date, admission date, discharge date, and date of death.
  - iii) A Limited Data Set **must exclude all** of the following *direct identifiers* of the individual or of the individual's relatives, employers, or household members of the individual:
    - (1) names;
    - (2) postal address information *other than town or city, state, and zip code*;
    - (3) telephone numbers;
    - (4) fax numbers;
    - (5) electronic mail addresses;
    - (6) social security numbers;
    - (7) medical record numbers;
    - (8) health plan beneficiary identifiers;
    - (9) other account numbers;
    - (10) certificate/license numbers;
    - (11) vehicle identifiers and serial numbers, including license plate numbers;
    - (12) device identifiers and serial numbers;
    - (13) web universal resource locators (URL);
    - (14) internet protocol (IP) address numbers;
    - (15) biometric identifiers, including finger and voice prints;
    - (16) full face photographic images and any comparable images; and
    - (17) any other number, characteristic or code that could be used to identify the individual.
  - iv) A Limited Data Set may be used or disclosed only if there is a **Data Use Agreement** (available from Appendix F of VHA Handbook 1605.1 - [http://www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=1423](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1423)) between the VHA and the recipient of the limited data set. The Data Use Agreement is intended to provide assurance of the limited use or disclosure of the information in the limited data set.
  - v) The Data Use Agreement must specify the following:
    - (1) the permitted uses and disclosures of information by the recipient, consistent with the purposes of the research;
    - (2) the limits on who may use or receive the data;
    - (3) that the recipient will not re-identify the data or contact the individuals; and
    - (4) that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the Privacy Rule and data use agreement or as required by law.
  - vi) A VHA investigator must submit a Data Use Agreement to the IRB for review and approval prior to releasing a limited data set from the VHA.
- k) **Minimum Necessary:** The Privacy Rule restricts use and disclosure of PHI. However, it does contain exceptions granting access in certain circumstances. Underlying all the exceptions, however, is the principle that any access should be limited to the minimum amount of information necessary to accomplish the intended purpose of the use or

disclosure. This standard requires VHA researchers to evaluate the needs of his or her study and request access only to those pieces of information necessary for the complete and accurate development of the research.

- l) Individual's Right to Access and Amend PHI:** As a general rule, individuals who participate in research have a right to access their own PHI maintained in a Designated Record Set (DRS). However, individuals participating in research protocols that include treatment (e.g., clinical trials) may be denied access to their PHI obtained in connection with that research protocol, provided
- i) the PHI was obtained in the course of the research;
  - ii) the individual agreed to the denial of access in the Research Authorization;
  - iii) the research remains in process; and
  - iv) the individual's rights to access such PHI are re-instated once the research study has ended and the Research Authorization has expired.
- m) Individual's Revocation of Research Authorization:**
- i) As a general rule, an individual may revoke his/her authorization, in writing to the Principal Investigator, at any time.
  - ii) The revocation will be applicable to the protocol or protocols specified by the individual.
  - iii) If the individual revokes his/her authorization, he/she may not be able to continue participation in the research project(s) that he/she specified in the original informed consent document. The revocation of authorization will not affect the individual's right as a VHA patient if he/she is a VHA patient.
  - iv) The researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual in good faith prior to receipt of the revocation of authorization. If the individual's information has already been combined with other participants' information in the study, such as when numbers are averaged, or if it has been sent to the study sponsor, the investigator may continue to use it, but no further information about the individual will be collected after he/she revokes his/her authorization.
  - v) The Principal Investigator shall keep copies of all revocations of authorizations for a specific protocol, and report them to the IRB at the time of continuing review.
  - vi) When authorization is revoked, the investigator or designee shall promptly notify the Research Office. The Research Office, in turn, will promptly notify the Privacy Officer and, if it is for a patient with a sensitive record, the Information Security Officer.
- n) Business Associates:**
- i) Business Associates who will receive VA patients' PHI must enter into a Business Associate Agreement with the VHA prior to the release of the VA patients' PHI.
  - ii) VHA Investigators with questions regarding whether or not a business associate agreement should be entered into with an entity should contact the Technical Information Specialist in the Research Service Office.



iii) The VHA Contracting Office will process Business Associate Agreements.

o) **Accounting of Disclosures:** As a general rule, a VHA patient has a right to receive an accounting of disclosures of their PHI for research purposes that have been made over the six years prior to the request unless such disclosure was made pursuant to an authorization, or is part of a Limited Data Set. However, this does not include disclosures prior to April 14, 2003.

i) The Principal Investigator must keep records of all disclosures of PHI in the following circumstances:

- (1) Disclosures pursuant to an IRB waiver;
- (2) Disclosures of PHI used in preparation of a research protocol; and
- (3) Disclosure of a decedent's PHI used for research.

ii) If the research involves disclosure of PHI involving <50 individuals when an authorization from the subject has not been obtained, the Principal Investigator must keep an account of the disclosure including the following:

- (1) Date of the disclosure
- (2) Description of PHI disclosed
- (3) Statement of purpose and basis of the disclosure
- (4) Frequency, periodicity or number of disclosures made during the accounting period
- (5) Date of last disclosure during the accounting period
- (6) Name of research or person who received the PHI and address of that individual.

iii) If the research involves disclosure of PHI involving >50 individuals when an authorization from the subject has not been obtained, the individual should be provided a list of research protocols in which the individual's PHI *may have been used*. The Principal Investigator must keep an account of the disclosure including the following:

- (1) The name of the protocol or other research activity;
- (2) A description of the purpose of the study;
- (3) The type of PHI disclosed;
- (4) The timeframe during which such disclosures occurred and
- (5) The name, address and telephone number of
- (6) the entity sponsoring the research, and
- (7) the researcher(s) or others to whom the data/information was disclosed.

**p) Notice of Privacy Practices**

i) VHA patients must receive a Notice of Privacy Practices (NPP). Many VHA patients will probably receive this Notice of Privacy Practice prior to participating in a research study. If a VHA patient has not previously received an NPP, the researcher must provide one (available at [http://www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=1089](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1089)).

**q) Data Use-Data Transfer Agreements:**

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- i) A combined Data Use Agreement (DUA)-Data Transfer Agreement (DTA) is required under the following circumstances:
    - (1) Data are transferred for research or research preparation from one VA facility to another VA facility;
    - (2) Data are transferred from one VA investigator or data owner or administrator (e.g., administrator of a Veterans Integrated Service Network (VISN) data warehouse, a national database, or a research data repository) to a VA investigator for a VA-approved research project or for research preparation;
    - (3) Data are transferred from a VA investigator to a non-VA person or entity who is servicer as a contractor or collaborator on a VA-approved protocol.
  - ii) A DUA-DTA is not required under the following circumstances:
    - (1) Data are transferred (disclosed) to a research sponsor in accordance with the VA-approved protocol and signed research informed consent documents and HIPAA authorizations;
    - (2) Data are transferred from one VA to another, the transfer is required to conduct and described in a VA-approved protocol, and the protocol is approved by each site's IRB.
    - (3) Data are disclosed to a non-VA individual or entity for research purposes and
      - (a) A signed research informed consent and signed HIPAA authorization has been obtained from each research subject OR
      - (b) A written request for the data has been received by the Privacy Officer and s/he has determined that release meets all requirements of the Privacy Act, HIPAA, and other applicable regulations, and all other applicable approvals have been obtained (see VHA Handbook 1605.1).
  - r) **Use or Disclosure of Psychotherapy Notes:** Authorization for use or disclosure of psychotherapy notes must not be combined with any other authorization for use or disclosure, unless the other authorization is also for a use or disclosure of psychotherapy notes.
- 7) **REFERENCES:** VHA Handbook 1605.1, Privacy and Release of Information; VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research; VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research; Department of Health and Human Services - Standards for Privacy of Individually Identifiable Health Information; Office of Civil Rights HIPAA Privacy Guidance Research.
- 8) **CONCURRENCES:** Endorsed by the Research & Development Committee 5/7/2012.
- 9) **RESCISSION:** HRPP: Health Insurance Portability and Accountability Act (HIPAA) in Human Subjects Research 8/29/2011.
- 10) **FOLLOW-UP RESPONSIBILITY:** ACOS, Research & Development Service (R&D)

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**Michael P. Davey, M.D., Ph.D.**  
**ACOS, Research & Development Service**